PSJ3
Exhibit 499

HDMA
Healthcare Distribution Management Association

Government & Public Policy Council (GPPC) and Specialty and Biotech Distributors Council (SBDC) Meeting

February 7-8, 2013

Renaissance Capital View Hotel
2800 South Potomac Avenue
Arlington, VA 22202-3592
(703-413-1300)

HDMA
Healthcare Distribution Management Association

Healthcare Distribution Management Association
Government and Public Policy Council (GPPC)
& Specialty and Biotech Distributors Council (SBDC) Meeting

February 7-8, 2013
Renaissance Arlington Capital View Hotel
2800 South Potomac Avenue
Arlington, VA 22202

AGENDA

Thursday, February 7

6:00 – 9:00 pm **Welcoming Reception/Dinner for IRC/GPPC/SBDC – Studio D**
Renaissance Arlington Capital View Hotel

Friday, February 8

7:30 am **Breakfast – Potomac Ballroom**
Renaissance Arlington Capital View Hotel

8:00 a.m. **Welcome and Introductions – Potomac Ballroom** **TAB 1**
John Gray, HDMA President & CEO
- Review Anti-trust & Anti-harassment Policy
- Review Agenda, Council Co-Chairs

GPPC
Ann Berkey, McKesson
Meg Glazier, Burlington

SBDC
Gayle Johnston, CuraScript SD
Walter Shikany, Health Coalition, Inc.

IRC
Chris Smith, HD Smith
Michael Conley, Novartis

8:05-9:15 a.m.	**GPPC/SBDC/IRC Joint Session – Potomac Ballroom**	
8:10-8:30 a.m.	• Overview of PR Campaign on Controlled Substance Abuse ***Mike Tuffin, Managing Director, APCO's Washington DC office***	**TAB 2**
8:30-9:00 a.m.	• 113th Congressional Session Overview ***Denzel McGuire, Policy Advisor to Senate Republican Leader Senator Mitch McConnell***	**TAB 3**
9:15-12:00 pm	**GPPC/SBDC Breakout Session – Salons 1-3** **Call-in #1-888-206-2266** **Guest ID #3665230**	
	• Approve Minutes from October GPPC Meeting	**TAB 4**
	• Dashboard Review	**TAB 5**
	• Regulatory Affairs Update – DEA Proposed Rule – FDA Hydrocodone Hearing	**TAB 6**
	• State Affairs Update	**TAB 7**
	• Trade Agreements Act	**TAB 8**
	• Update on Federal Pedigree Activities	**TAB 9**
	• ASP/Prompt Pay Discount	**TAB 10**
11:30-12:00 pm	**Special Guest Speaker at GPPC/SBDC Breakout Session** ***Dan Todd, Health Policy Advisor, U.S. Senate Finance Committee***	**TAB 11**
12:00-1:30 pm	**Joint Luncheon w/Guest Speaker – Potomac Ballroom** ***Fred Barnes, Weekly Standard***	**TAB 12**

HDMA
Healthcare Distribution Management Association

ANTITRUST POLICY

It is the unqualified policy of HDMA and all of its operating committees to conduct their operations in strict compliance with the antitrust laws of the United States.

HDMA's antitrust policy prohibits any discussions which constitute or imply an agreement or understanding concerning: 1) prices, discounts, or terms or conditions of sale; 2) profits, or profit margins or cost data; 3) market shares, sales territories or markets; 4) allocation of customers or territories; 5) selection, rejection or termination of customers or suppliers; 6) restricting the territory or markets in which a company may resell products; 7) restricting the customers to whom a company may sell; or 8) any matter which is inconsistent with the proposition that each member company of HDMA must exercise its independent business judgment in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

HDMA membership, Board of Directors and committee meetings shall be conducted pursuant to agendas distributed in advance to attendees; discussions shall be limited to agenda items which have been reviewed by HDMA legal counsel; there shall be no substantive discussions of HDMA matters other than at official meetings; and minutes shall be distributed to attendees promptly upon review by HDMA legal counsel.

HDMA
Healthcare Distribution Management Association

A. SEXUAL AND OTHER UNLAWFUL HARASSMENT POLICY

It is HDMA's policy that all of our employees should enjoy a work atmosphere free from all forms of discrimination, including sexual or other unlawful harassment.

HDMA prohibits harassment of its employees by anyone: supervisors, other employees, members, vendors, visitors or any other business contacts. Employees are similarly prohibited from harassing coworkers, members, vendors, visitors or any other business contacts. This policy applies at HDMA's offices and also to company-sponsored events, offsite meetings, business travel, and occasions where employees gather or interact.

1. Sexual Harassment

The EEOC has defined sexual harassment as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature when (1) submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment; (2) submission to or rejection of such conduct by an individual is used as the basis for employment decisions affecting such individual; or (3) such conduct has the purpose or effect of unreasonably interfering with an individual's work performance or creating an intimidating, hostile or offensive working environment.

Conduct that may constitute sexual harassment includes, but is not limited to:

- Promising, directly or indirectly, an employee a reward if the employee complies with a sexually-oriented request;
- Threatening, directly or indirectly, to take action against an employee if the employee refuses to comply with a sexually-oriented request;
- Engaging in sexually suggestive physical contact, including touching another employee in a way that is unwelcome;
- Making unwanted sexual or romantic advances toward an employee, or persisting in such conduct despite the employee's rejection of the advances;
- Abusive language related to an employee's sex, including sexual innuendoes and slurs;
- Suggestive, derogatory or insulting comments or sounds, including whistling and obscene gestures;
- Comments about someone's body;
- Jokes, cartoons or pictures of a sexual nature or concerning gender-specific traits;
- Disparaging or demeaning comments about gender; and
- Words or pictures describing or displaying pornographic or sexually explicit material.

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2. Other Unlawful Harassment

Unlawful harassment based on protected characteristics other than sex also is prohibited. Harassment based on categories other than sex can be defined as verbal or physical conduct that denigrates or shows hostility or aversion towards a protected group or against an individual because of membership in such a group, when that conduct:

- Has the purpose or effect of creating an intimidating, hostile or offensive working environment;
- Has the purpose or effect of unreasonably interfering with an individual's work performance; or
- Otherwise adversely affects an individual's employment opportunities.

Conduct that constitutes unlawful harassment on the basis of an individual's legally protected characteristics includes, but is not limited to:

- Epithets, slurs or negative stereotyping;
- Threatening, intimidating or hostile acts based on an individual's membership in a protected class;
- Denigrating jokes, cartoons or pictures based on legally protected characteristics;
- Display or circulation in the workplace of written or graphic material (including email) that denigrates or shows hostility or aversion towards an individual or group based on a protected category.

3. Complaint and Investigation Procedures

It is the responsibility of each employee to enforce and comply with these policies. If you believe you have been harassed or discriminated against or have witnessed or been told about discrimination or harassment in violation of these policies, you must immediately notify the Senior Director, HR, the President or any member of management with whom you feel comfortable. Supervisors have an obligation to report all incidents of possible discrimination or harassment which they experience, witness or of which they become aware. Any supervisory employee who experiences, witnesses or becomes aware of harassment and fails to report it to the Senior Director, HR or the President will be disciplined up to and including termination.

HDMA will conduct a thorough, impartial and prompt investigation of all complaints. Investigations will typically be conducted by the Senior Director, HR. A complaining employee may be asked to put his or her complaint in writing in order to assist with the investigation. The investigation normally will include discussions with the complaining party, any other person who experienced or witnessed the alleged discriminator or harassment and the accused. Relevant documents also may be reviewed. Upon completion of the investigation, if any discrimination or harassment in violation of these policies is found to have occurred, HDMA will take prompt and effective remedial action to stop the discrimination or harassment, including without limitation disciplining and/or discharging employees who have violated the policy. If a non-employee is found to have violated one of these policies, HDMA will also take effective remedial action to the fullest extent feasible. Generally, the employee who initiated the complaint will be informed of the outcome of the investigation. However, specific disciplinary action taken against any employee as a result of the investigation will not necessarily be disclosed.

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HDMA will protect the confidentiality of the complaining employee, witnesses and the accused except to the extent necessary to conduct a thorough investigation or to remedy a problem discovered as part of the investigation. We also request that anyone complaining of harassment or participating in an investigation as a witness maintain the confidentiality of the investigation.

It is unlawful to retaliate against an employee for filing a complaint of harassment or for cooperating in an investigation of such a complaint. HDMA strictly prohibits retaliation or discrimination in any form against anyone who, in good faith, has reported harassment or discrimination, or who has participated in any manner in an investigation under this policy. Any person who believes they have been improperly retaliated or discriminated against in violation of this policy should follow the complaint procedure set forth above.

If you have any questions about this policy, please contact the Senior Director, HR.

Violations may also be reported in any of the following ways:

- Directly to the in-house Compliance Officer
- Directly to the Senior Director, HR
- Anonymously through the toll free Whistleblower Hotline: 800-398-1496
- Anonymously through E-mail to: reports@lighthouse-services.com
- Anonymously through the Web: lighthouse-services.com (click on Report Incident link).
- Username: HDMA and Password: 901Glebe

When using the anonymous reporting system, your complaint will be recorded by a third party vendor, which will relay the information to the Compliance Officer.

COMPLAINTS AT HDMA OFF SITE MEETINGS SHOULD BE IMMEDIATELY DIRECTED TO HDMA'S VICE PRESIDENT, MEETINGS & CONFERENCES OR THE SENIOR DIRECTOR, HUMAN RESOURCES.

As of 2/2013

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Government and Public Policy Council

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Michael Tuffin

Michael Tuffin, managing director of APCO Worldwide's Washington, D.C., office, is an accomplished strategist with extensive experience in public policy, health care and national politics. He previously served as executive vice president at America's Health Insurance Plans (AHIP), where he led public affairs strategy for the industry at the center of the national debate on health care reform. Mr. Tuffin's responsibilities included communication, advertising, media relations, new media, grassroots advocacy and management of AHIP's Center for Policy & Research. He also represented the health insurance industry on a wide range of national news programs.

Prior to joining AHIP, Mr. Tuffin served as a vice president at APCO, where he helped launch a flagship pharmaceutical industry prescription assistance campaign and directed a major retirement security initiative backed by a broad-based coalition of leading national business associations. As a consultant, he periodically appeared on BBC television and radio, offering insights on American politics to a global audience. Mr. Tuffin previously served as senior director of strategic communications at the Pharmaceutical Research and Manufacturers of America (PhRMA).

Earlier in his career, Mr. Tuffin worked on a wide range of political campaigns, holding key positions on two presidential bids. In 1996, he directed communications for the successful referendum campaign that enabled the NBA's Miami Heat to build the American Airlines Arena. From 1993-1995, he worked on legislative staffs in the U.S. Senate and U.S. House of Representatives, focusing on economic and fiscal issues.

Mr. Tuffin holds an MBA with a finance concentration from the Owen Graduate School of Management at Vanderbilt University and an economics degree from Providence College.

Denzel McGuire

Denzel currently serves as chief policy advisor on budget, appropriations and education issues to Senator McConnell, the Senate Republican Leader. She is key policy advisor on fiscal issues and participated in the Biden Group and Super Committee discussions in 2011 and the recent fiscal cliff negotiations. Prior to working for Senator McConnell, she served as Deputy Chief of Staff/Policy Director to Senator Kyl, the Republican Whip and as Minority Staff Director for the Budget Committee for Senator Gregg. Although Denzel has an extensive background in fiscal issues, her initial policy expertise was in education. She was the chief staff negotiator on NCLB for Senate Republicans and worked on the Education and Workforce Committee for Congressman Goodling. She is a graduate of UVA.

OFW DRAFT

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

GOVERNMENT AND PUBLIC POLICY COUNCIL AND SPECIALY AND BIOTECH DISTRUBTION COUNCIL MEETING MINUTES

September 18, 2012
K&L Gates LLP
Washington, D.C.

I. ATTENDEES

A. Government and Public Policy Council

1. Members Available

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Greg Drew, Co-Chair	President Value Drug Company
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James Edwards	Chief Financial Officer Dakota Drug, Inc.
Robert Giacalone	Senior Vice President, Regulatory Affairs and Chief Regulatory Counsel Cardinal Health, Inc.
David S. Moody	Chief Executive Officer

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	Mutual Wholesale Drug Co.
Robert Schwartz	Compliance Officer FMC Distributors, Inc.
Brian Tyler	President, McKesson U.S. Pharmaceutical Unit McKesson Corp.

B. SPECIALTY AND BIOTECH DISTRIBUTORS COUNCIL

1. Members Available

Gayle Johnston (Co-Chair)	President CuraScript SD Specialty Distribution, an Express Scripts Company
Walter Shikany (Co-Chair)	President and CEO Health Coalition, Inc.
Scot Buchanan	VP, Supply Chain Strategy AmerisourceBergen Corporation
Thomas Doyle	Vice President, Business Development/Specialty Solutions H. D. Smith
Abigail Jenkins	Vice President, Business Development Intellogics
Lenihan Keagan	Director, Federal Government Relations (for Jeff Reinke) McKesson Specialty Care Solutions
Cynthia Robbins	Vice President, Corporate Contracting BDI Pharma, Inc.
Mary Rosado	Vice President, Federal Government Affairs CuraScript SD Specialty Distribution, an Express Scripts Company
Geoff Werth	Director, Federal Government Relations McKesson Specialty Health

2. Members Unavailable

Robert Brown	Vice President, Sales Cardinal Health Specialty Solutions
Richard Gaton	President BDI Pharma, Inc.
Jonah Houts	Senior Director, Federal Government Affairs CuraScript SD Specialty Distribution
Jeff Reinke	Vice President & GM, Distribution Oncology Sales McKesson Specialty Care Solutions
Amy Valley	Director of Marketing, VitalSource GPO

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	Cardinal Health Specialty Solutions

C. HDMA STAFF

John Gray	President and CEO
Patrick Kelly	Senior Vice President, Government Affairs
Elizabeth Gallenagh	Vice President, Government Affairs
Anita Ducca	Vice President, Regulatory Affairs and General Counsel
John Parker	Vice President, Communications
Kristen Freitas	Senior Director, Federal Government Affairs
Daniel Bellingham	Senior Director, State Government Affairs
Elizabeth Lankford	Manager, State Government Affairs
Allison Wiley	Regulatory Affairs and Healthcare Policy Analyst
Pamela Ritter	Administrator
Karen J. Ribler	Executive Vice President & COO Center for Healthcare Supply Chain Research

D. GUESTS

Tucker Carlson	Contributor, FOX News; Editor-in-Chief, The Daily Caller; Senior Fellow, The Cato Institute
Elizabeth Campbell	AmerisourceBergen Corporation Guest of Chris Zimmerman
Rai Downs	Tarplin, Downs and Young
Keith Flanagan	Senior Health Counsel U.S. Senate Committee on Health, Education, Labor & Pensions (HELP)
George Koch, Esq.	K&L Gates
Buddy Menn	Brown Rudnick
Larri Short, Esq.	Arent Fox LLP
Linda Tarplin	Tarplin, Downs & Young LLC
Jennifer Young	Tarplin, Downs & Young LLC

E. LEGAL REPRESENTATION

Tish E. Pahl, Esq.	Olsson Frank Weeda Terman Matz PC
Jon M. Weinrieb, Esq.	Olsson Frank Weeda Terman Matz PC

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II. JOINT GPPC//SBDC/IRC SESSION I (Agenda Items #1-3; Tab 1 of meeting binder)

A. Welcome and Introductions

John Gray called the joint session of the Government and Public Policy Council (GPPC), Specialty & Biotech Distributors Council (SBDC), and Industry Relations Council (IRC) to order at approximately 8:00 a.m. on September 18, 2012. Perry Fri and Patrick Kelly welcomed Council members. Self-introductions followed.

B. Review of Antitrust & Anti-Harassment Policies (Tab 1 of meeting binder)

Counsel for HDMA, Tish Pahl, reviewed the HDMA antitrust and anti-harassment policies for all attendees.

C. Guest Speakers (Tab 2 of meeting binder)

1. Linda Tarplin and Buddy Menn

Brown Rudnick Principal, Henry ("Buddy") Menn, III, and Tarplin, Downs & Young, LLC, co-founder, Linda Tarplin, provided an overview of potential impacts that the upcoming Presidential and Congressional elections could have on the financial markets and the so-called "fiscal cliff" eventuality. They also commented on the relative challenge that it will be to advance several pharmaceutical supply chain-related initiatives in the impending "lame duck" Congress, such as Average Sales Price (ASP) reimbursement and federal pedigree.

2. Jennifer Young and Larri Short

Tarplin, Downs & Young, LLC, co-founder, Jennifer Young, and Arent Fox LLP partner, Larri Short, spoke to issues concerning the Physician Payment Sunshine Act provisions of the Affordable Care Act (ACA), Average Manufacturer Price (AMP), Average Wholesale Price (AWP) and ASP. They also discussed the potential impacts that the upcoming Presidential election could have on implementation of the ACA. Ms. Short and Ms. Young believe it is unlikely that any ACA-related regulations will be promulgated prior to 2013.

III. GPPC/SBDC BREAKOUT SESSION I

A. Welcome and Administrative Matters (Tab 3 of meeting binder)

Mr. Kelly welcomed members and guests to the GPPC/SBDC breakout session and outlined the agenda for the day. Self-introductions followed.

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Mr. Kelly turned the GPPC/SBDS's attention to the draft minutes from the May 15, 2012 conference call.

Action: On motion duly made and seconded, the GPPC/SBDC unanimously approved the Minutes of the May 15, 2012 conference call.

B. GPPC/SBDC Initiatives And Activities

1. Drug Shortages/Gray Market (Tab 4 of meeting binder)

Ms. Kristen Freitas discussed recent, vigorous federal legislative activity in the area of drug shortages and so-called "gray market" distribution of drug products. Mr. Gray testified before the Senate Commerce, Science and Transportation Committee on July 25, 2012. Mr. Gray also testified before the House Energy and Senate Commerce Health Subcommittee. Additionally, the House Oversight and Government Reform Committee held a hearing at which Chairman Issa (R-CA) focused upon the extent to which Food and Drug Administration (FDA) actions were contributing to shortages.

HDMA staff believes the hearings have gone well for primary wholesale distributors and that members' story has been communicated. The Senate Commerce Committee had additional questions to which HDMA responded on August 31, 2012. Senator Rockefeller (D-W.Va.), and Rep. Cummings (D-MD) are expected to release a report on the "gray market" for pharmaceuticals, particularly those drugs that are in short supply.

The Prescription Drug User Fee Act reauthorization, the FDA Safety and Innovation (Public Law 112-144), was recently enacted. It does not contain any requirements that wholesale distributors report information concerning drug shortages.

Senator Hatch (R-Utah) is circulating a draft to address shortage issues, including the extent to which reimbursement policies may be exacerbating the problem. The draft would provide incentives to increase the numbers of manufacturers making products. Further, for sterile injectable products with four or fewer manufacturers, the legislation would set reimbursement at ASP + 6% and freeze 340B and Medicaid rebates for 7 years. Congressman Cassidy (R-LA) may introduce legislation as a companion to the eventual Hatch bill.

Ms. Freitas reported that the HDMA Federal Government Affairs Committee recommends supporting the Hatch draft; however, no action is expected this year.

Congressman Cummings (D-MD) has introduced H.R. 5853. Among other things, the legislation would prohibit wholesalers from buying from pharmacies, a limitation HDMA

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supports. If enacted, the law would also establish a national wholesaler database and require inclusion of sales price information on drug pedigrees.

It is unclear where other stakeholders stand on these legislative proposals. HDMA staff has not yet heard what position pharmacies are taking on H.R. 5853. The issue of drug shortages is a difficult one for GPhA and there are conflicting views..

Discussion ensued. The GPPC/SBDC advised HDMA staff to continue to closely monitor these bills and the issues surrounding drug shortages. Any final bill, whether offered by Hatch-Cassidy, Cummings, or from another source, will need to be reviewed to determine if HDMA should support it and how strongly.

2. ASP/Prompt Pay Discount (Tab 5 of meeting binder)

Ms. Freitas discussed efforts to address the ASP and prompt pay discount. Specifically, HDMA is supporting H.R. 905 and the related S. 733 which would amend the Social Security Act to exclude customary prompt pay discounts from manufacturers to wholesalers from the ASP. However, the provision is scored and so will cost funds to implement. HDMA signed on to a coalition letter urging the provision be included in any new legislative vehicle and to hopefully be addressed in the sequestration discussions. If the fiscal cliff occurs without resolution of the ASP issue, there will be an automatic 2% cut in reimbursement as of January 1, 2013.

3. Last In, First Out (LIFO) Update

Ms. Elizabeth Gallenagh updated the GPPC/SBDC regarding ongoing discussion of repeal of the LIFO method of accounting which, if enacted, would be highly detrimental to wholesale distributors. Ms. Gallenagh stated that currently there are no pending federal bills to eliminate LIFO but, as deficit reduction talks continue, that LIFO repeal remains an appealing option for raising revenue. Ms. Gallenagh sought the views of the GPPC/SBDC going forward on LIFO repeal and presented three position options:

1. HDMA continues to remain categorically opposed to LIFO repeal and will stay in league with the National Association of Wholesaler-Distributors (NAW) so long as NAW remains categorically opposed to LIFO repeal.

2. HDMA could broach the idea of a compromise with a move away from LIFO prospectively.

3. HDMA could suggest LIFO repeal in exchange for a reduction in the corporate income tax rate.

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Discussion ensued. Consensus arose in the GPPC/SBDC that HDMA should continue to pursue option 1. HDMA members continue to remain opposed to any LIFO repeal.

4. Controlled Substances and Diversion (Tab 7 of meeting binder)

Mr. Kelly introduced the topic of HDMA activities regarding controlled substances and diversion. HDMA has formed a Controlled Substances Task Force whose purpose will be to formulate a comprehensive policy and set of messages that encompasses federal and state legislative activity, regulatory initiatives, enforcement, and a public affair strategy. The first step in this process is to review the many ongoing issues and consider which to include in HDMA's legislative and public affairs "package." HDMA staff needs guidance from the GPPC/SBDC regarding if and how members wish for HDMA to become more proactive in this area. Staff will take the recommendations of the GPPC/SBDC to the HDMA Board for its approval.

a) Public Relations Strategy

Mr. John Parker began describing the challenging landscape with regard to controlled substances. Mr. Parker explained that the "drumbeat" regarding use and abuse of controlled substance is loud, painful and consistent. For example, prescription drug abuse is considered an "epidemic" by the Centers for Disease Control and Prevention (CDC). Furthermore, the Drug Enforcement Administration (DEA) considers prescription drug abuse a top enforcement priority and there have been lawsuits and enforcement actions that characterize HDMA's wholesale distributor members in very misleading ways.

A part of the challenge going forward is how to present the facts about wholesale distributors, abuse and diversion; for instance, 70% of abusers obtain their drugs from friends and family. Focusing enforcement efforts on wholesale distributors does not solve the problem of abuse and diversion. Mr. Parker presented several options for discussion, including:

- Participation in an issue paper under the auspices of the National Governors' Association (NGA)
- Development of a comprehensive public affairs strategy
- Education
- Building alliances with other stakeholders

HDMA has been exploring retaining a public relations firm to assist with the controlled substance messaging strategy. HDMA staff has met with four firms and two firms will be presented to the Board in October. HDMA believes it is very important for all members to evaluate this possible new direction and more proactive level of engagement.

The proposals from the public relations firms include the following:

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- Stakeholder research
- Message development
- Media relations – crisis and proactive
- Educational toolkit
- Alliance development

Other ideas suggested by the public relations firms include:

- Closed-door stakeholder summit
- Independent advisory commission
- White hat issue campaign
- Advertising
- State and local strategies
- Websites, microsites, social media

Discussion ensued as members carefully considered this proposal. GPPC/SBDC members asked HDMA staff to forward the public relations firm recommendations and proposals so that they could discuss the issue with their own upper management and public affairs staff in advance of the Board meeting. There was consensus in the GPPC/SBDC supporting consideration of the public relations firms and recognition of the need for wholesale distributors to be more proactive in stating their positions and practices regarding controlled substances.

Action: HDMA staff will provide the information about the public relations firm initiatives to those GPPC/SBDC members who request it.

b) NGA

Mr. Kelly discussed HDMA's participation in the NGA initiative regarding controlled substance use and abuse. HDMA has helped fund the initiative and participates to assure that the role of distributors in a secure supply chain is presented accurately and understood. The Office of National Drug Control Policy (ONDCP) is actively involved in the initiative, is very influential with the DEA, and recognizes the need for a very broad approach that does not focus exclusively upon distributors, pharmacies and enforcement.

NGA has identified best practices and will be convening with senior health officials from six states to try to develop best practices for states on controlled substance use and abuse prevention. Issuance of a white paper and guidance will follow. HDMA also contacted Carmen Catizone of the National Association of Boards of Pharmacy to speak on prescription drug monitoring programs (PDMPs) at the next HDMA Board meeting.

Action: HDMA staff will provide to GPPC/SBDC members the names of the officials from the six states who are participating in this best practice development. The

GPPC/SBDC instructed HDMA to be sure to include the HDMA State Government Affairs Committee (SGAC), as members of that committee have good contacts at the state level in public health regulation and enforcement.

c) Federal Legislative Issues (Tab 7 of meeting binder)

Ms. Gallenagh and Ms. Freitas presented on federal legislative issues involving controlled substances. Tab 7 of the meeting binder summarized the status of major initiatives, HDMA staff's recommendations, and where the views of the GPPC/SBDC were sought. HDMA continues to support:

- Increased penalties for cargo theft
- Interoperability standards and federal funding for PDMPs
- Increased penalties for pill mills and
- Prohibition on wholesalers purchasing from pharmacies

Additionally, there may be an opportunity to support a model federal bill to obtain greater clarity from DEA on a variety of controlled substance issues, particularly related to suspicious orders handling. A new model bill on prescription drug abuse might also be proposed.

Discussion ensued. GPPC/SBDC members commended HDMA staff on its management thus far of possible federal legislation. GPPC/SBDC asked that HDMA staff continue to engage on these issues as they have.

As to the possibility of a model bill, consensus emerged that developing and lobbying for a model bill is a significant commitment. Such a task should not be undertaken without first consulting with the HDMA Board and developing a long term strategy for engaging on the issue. The Board must decide if HDMA should remain in its reactive stance or become more proactive.

d) State Legislative Issues (Tab 7 of meeting binder)

Mr. Dan Bellingham presented to the GPPC/SBDC on state issues of importance to members. Issues likely to arise in the next state legislative sessions include:

- Doctor shopping/Pill Mills
- Prohibition on wholesalers purchasing from pharmacies
- PDMPs
- E-prescribing of controlled substances

HDMA staff recommends that the association become more proactive in its support for legislation and regulation of the following:

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- Pain clinic licensing and increasing penalties for violations
- Prohibiting individuals from purchasing multiple prescription drugs from different doctors, so-called "doctor shopping"
- Prohibiting wholesalers from purchasing pharmacies

Discussion ensued and there was general support for HDMA staff's recommendations.

HDMA staff also recommends becoming more proactive in support of PDMPs with support for federal interoperability standards. General discussion ensued with recognition that there were many hurdles and issues to be resolved for PDMPs to be truly useful. GPPC/SBDC members agreed that HDMA should continue support for PDMPs, but should be cognizant of potential efforts to shift program costs to distributors.

Mr. Bellingham also discussed changes to law to permit electronic prescribing of controlled substances. HDMA staff believes that the National Association of Chain Drugstores (NACDS) supports e-prescribing and that the National Community Pharmacists Association (NCPA) has concerns. Discussion ensued with consensus for supporting the position of members' pharmacy customers as the pharmacy associations begin to articulate those positions.

Other important state and federal issues include:

- Hydrocodone scheduling
- Stronger wholesaler licensing
- Controlled substance sales reporting
- Drug disposal
- Prescriber education

Discussion ensued with consensus developing that HDMA should continue to support these initiatives as it has.

C. Mr. Keith Flanagan Presentation

Mr. Keith Flanagan, Senior Health Counsel, U.S. Senate Committee on Health, Education, Labor & Pensions (HELP) spoke to the GPPC/SBDC. Mr. Flanagan discussed the current legislative landscape and shared insights into fiscal cliff discussions. He discussed the current status of potential federal pedigree and track and trace legislation. He emphasized that legislators are very concerned about increased business costs and that if members have concerns about any legislation, they should be certain to analyze the relevant business costs and be prepared to educate legislators and staff on those issues.

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IV. JOINT IRC/GPPC/SBDC SESSION II – LUNCHEON

HDMA members and staff welcomed guest speaker, Tucker Carlson, Contributor, FOX News, Editor-in-Chief, The Daily Caller, and Senior Fellow, The Cato Institute. Mr. Carlson spoke on issues concerning the upcoming Presidential election and the future of the country's two-party political system. Mr. Carlson was thanked for attending the joint Council session.

V. GPPC/SBDC BREAKOUT SESSION II

A. Federal and State Pedigree

Ms. Gallenagh led a discussion of Mr. Flanagan's presentation and the status of federal pedigree legislation, as well as potential timing and to what bill the proposal might attach. Discussions and work continue. Implementation of the California pedigree is ongoing with some stakeholders still vowing to fight it and others worried that if a federal pedigree solution does not arise soon, it will be too late to do anything but comply with California law. There remains a lot of fragmentation and disagreement among certain stakeholders.

Ms. Gallenagh also described the status of the meetings with the California Board of Pharmacy. Issues continue to require work, including which orders, products, and shipment would be subject to inference. HDMA staff and members have good relations with the California Board and staff is optimistic that this good work can continue.

Some stakeholders continue to advocate delaying implementation of the California law. HDMA staff recommends that the association avoid involvement in the delay activities, but still monitor the situation closely. Staff further does not recommend any policy shift in California. Rather, HDMA staff recommends continuing to focus on implementation of California law, its positive working relationship with the board, and a potential federal pedigree solution. Discussion ensued.

GPPC/SBDC members agreed with HDMA staff recommendations and the approach presented.

Further discussion ensued about the point Mr. Flanagan raised regarding cost estimates of implementing a federal pedigree solution. The GPPC/SBDC discussed how the different affected players might conduct research and document the business costs associated with such legislation. Pew is conducting an analysis and has asked the different stakeholder associations, including HDMA, to collect information from members and submit it to Pew for calculation of supply chain costs to implement a federal pedigree legislative solution.

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Discussion ensued regarding whether HDMA should participate in the Pew study. There was uncertainty regarding what pedigree system Pew was studying, which was important information, as the different models vary in complexity, scope and cost.

Members recommended that HDMA staff:

- Continue to support federal pedigree legislation.
- Offer to have a telephone conference with Pew to discuss the survey and learn what system they would be evaluating and estimating and what assumptions would be built into the survey.
- Have Booz & Company participate in the Pew conference call as the Booz consultants have a deep understanding of healthcare distribution models and surveys.
- Try to gain more insight into what Members of Congress and staffers would wish to see regarding cost estimates for implementation of a federal pedigree.

B. Controlled Substances Regulatory Issues

Ms. Anita Ducca presented to the GPPC/SBDC regarding regulatory pathways for further engagement with DEA. There continues to be intense DEA scrutiny of wholesale distributor activities and industry would benefit from greater clarity from the agency. Options for further engaging DEA to demonstrate wholesale distributors' limited role in diversion and abuse of controlled substances include:

- Petitioning DEA for changes to rules
- Updating the ICG
- Collecting ARCOS Data
- Obtaining distributor access to PDMP data
- Studying and establishing a customer algorithm/threshold
- Retaining a third-party to conduct an audit

Discussion ensued. GPPC/SBDC members recognized that any such effort would be significantly multi-faceted, with a regulatory, legislative, and communications strategy. Members recommended tabling further discussion of this proposed initiative until the Board meets and discusses the proposed public relations strategy.

C. Reimbursement Metrics (Tab 10 of meeting binder)

HDMA staff discussed the recent efforts to identify a reimbursement metric to replace the Average Wholesale Price (AWP). The Centers for Medicare & Medicaid Services (CMS) has been investing in the National Average Drug Acquisition Cost (NADAC) in which pharmacies are asked to submit invoice data for drug purchases. CMS has entered into a contract with Myers

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& Stauffer LC to perform surveys of National Average Retail Prices (NARP) and drug acquisition costs. Glass Box Analytics has created the Predictive Acquisition Cost (PAC) which was developed using data and analyses similar to those used in financial services to determine credit worthiness (FICO).

HDMA has concerns regarding the NARP and NADAC surveys. HDMA wishes to ensure that wholesalers do not have to report pricing data, that pharmacies are appropriately reimbursed, and that any data that is submitted be treated confidentially. HDMA expects to have additional conversations with CMS and Myers & Stauffer regarding these issues. Stakeholders share these and other concerns about the surveys.

HDMA's Reimbursement Task Force has discussed options as stakeholders and CMS continue work to find a new metric to replace AWP. HDMA staff asks for guidance from the GPPC/SBDC. Specifically, should the association:

1. Continue to monitor and advocate on issues of importance to members and pharmacy customers but otherwise remain neutral on CMS' NADAC development;
2. Support the PAC model of Glass Box Analytics; or
3. Support the development of a non-profit, FICO-like model.

Discussion ensued. GPPC/SBDC members recommended continuing with Option 1.

D. <u>Department of Transportation (DOT) Rules On Tote Markings</u> (Tab 11 of meeting binder)

Ms. Ducca presented on DOT rulemaking that would require replacing the current ORM-D marking with a new international black diamond on all reusable plastic totes that distributors use to ship product between distributions centers and customers. HDMA has opposed applying this rule to wholesale pharmaceutical distributors for several reasons, including:

- The plastic totes have very long, useful lives and it is expensive to replace them.
- The rule is intended for international harmonization and distributors are not shipping product internationally.
- There are logistical challenges to retrieving and replacing the totes.
- There is no public health benefit justifying the change.
- There is a negative environmental impact from the disposal of so many plastic totes.

HDMA has commented on the proposed rule and asked DOT that the marking requirements not apply at all, or, alternatively, that wholesale distributors have a longer period of time in which to transition to new totes. DOT has granted HDMA's request and currently is

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requiring compliance by January 1, 2016. HDMA staff seeks guidance from the GPPC/SBDC regarding whether HDMA should do anything further regarding tote markings. Options include:

1. Petition DOT to create an exception from the marking requirement for all plastic, reusable totes moving in domestic commerce.
2. As UPS was the prime mover of the rule change, ask UPS to inform DOT that it did not intend for the rule to apply to domestic totes.
3. Take no further action and await the final rule.

Discussion ensued. GPPC/SBDC members recommended continuing with Option 1.

E. U.S. Pharmacopeia (USP) Initiatives

Ms. Ducca discussed the ongoing issues arising with USP's guidance development. In January 2012, USP released a new Draft Chapter <1083> "Good Distribution Practices - Supply Chain Integrity." HDMA had numerous concerns about the draft and filed extensive comments. HDMA understands that USP intends further guidance development regarding "good distribution practices," including finalizing Chapter <1083> and additionally proposing guidances regarding supply chain controls, import and export practices, and supply chain integrity (including pedigree, serialization, and track and trace).

HDMA has significant concerns regarding USP's expansion into supply chain issues, particularly pedigree, serialization and track and trace where members and other important stakeholders have been working very hard on these complex issues for many years. HDMA has met with USP staff, attended a USP workshop and webinar, and is now seeking stakeholder allies who are also concerned with USP's guidance expansion plans.

HDMA staff seeks the views of the GPPC/SBDC on USP's proposed guidance expansion. Should HDMA:

1. Continue to seek stakeholder support and arrange a joint meeting with USP to emphasize stakeholder concerns.
2. Meet with USP alone.
3. Submit concerns to USP in writing.
4. Take no further action and await USP's next step.

Discussion ensued. GPPC/SBDC members recommended continuing with Option 1 and also asked HDMA staff to consider options 2 and 3 as well. There was consensus, however, that HDMA should be proactive and so option 4 was rejected.

F. Dashboard (Tab 13 of meeting binder)

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HDMA staff proposed the following changes to the Dashboard:

"A" Priorities

Regulatory

- MODIFY (from A1 to A2) *Drug Shortages/Product Availability*

"B" Priorities

Regulatory

- MODIFY (B2 to B1) *DOT Issues*
- MODIFY (B1 to B2) *Non-Approved Drugs*

Discussion ensued. GPPC/SBDC members recommended changing Patient Privacy/HIPAA from a "C2" Priority to "B2" under State Government Affairs. Members also asked that Mr. Kelly and Mr. Fri consult on the dashboard to assure consistency among GPPC/SBDC and IRC priorities.

Action: The GPPC/SBDC accepted all recommended Dashboard changes, including changing Patient Privacy/HIPAA from a "C2" Priority to "B2" under State Government Affairs.

* * *

There being no further business, the meeting adjourned at 3:00 p.m.

Prepared by:

_____
Tish E. Pahl, Counsel
Date: _____, 2012

Approved by:

_____
Patrick Kelly
Date: _____, 2012

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HDMA Issues / Initiatives
Dashboard - First Quarter 2013

Q1 2013
Updated: 02/04/13 - STAFF PROPOSED

	Initiative	Status							
		FGA	SGA	Reg	IR	PA	Cntr	Edu	SBDC
	A Priorities								
	340B Issues	2			2				2
	Biotechnology / Specialty				1	1	1	1	1
	Controlled Substance Issues	1	1	1	2	1		2	
	Distributor Licensing / Accreditation	1	1			1			
	Drug Shortages / Product Availability	1	2	2	1	1		1	1
	Generic Drugs: Issues	2	2		2	2	2		
	Healthcare Standards (Serialization, etc.)			1	1	2	2	1	
	Importation / Import Safety	1				1			
	Supply Chain Security	2	1	2	1	1	1	1	
	Marketing and Gift Restrictions		2	1					
	Medicaid: AMP / RSP / AAC / WAC	1	2	1	2	1		1	1
	Medicare: Part B ASP (Prompt pay/CAP)	1		2	2	2			1
	Pedigree Requirements	1	1	2	1	1	1	1	1
	Pseudoephedrine / Dextromethorphan	2	1	2					
	Role of Distributor Study					1	1		
↑	Rx Waste / Disposal / Take-Back	2	2	1	2		1	1	
	Tax Issues (Gross Receipts and LIFO)	1	1			1			
	Wholesaler Price Reporting		1	2					
	B Priorities								
	Cold Chain Best Practices			2	1		2	1	2
	Conditions for Safe Use			2					
	Contract Administration				1			1	
	Counterfeiting Alert Network (CAN)			2		1			
	DOT Issues			1					
	EDI Guideline Updates				1			1	
	Emergency Preparedness / Pandemic Influenza	2	2	2	1	2		2	
	Health, Beauty & Wellness				1	2		2	
	Internet Pharmacy	2		2					
	NDC Rule (Repackaging/Relabeling)			2	2	2			
	Non-Approved Drugs			2					
	PBM Transparency	2	2						
	Returned Goods		1	2	1	2	1	1	
	Risk Eval Mitigation Strategies (REMS)	2		2	2	2	1	2	
↑	~~Rx Waste / Disposal~~	~~1~~	~~1~~	~~1~~	~~2~~		~~1~~	~~1~~	
	Seasonal Influenza	2	2	2	2	2			

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HDMA Issues / Initiatives
Dashboard - First Quarter 2013

Q1 2013
Updated: 02/04/13 - STAFF PROPOSED

C Priorities

Initiative	Status: FGA	SGA	Reg	IR	PA	Cntr	Edu	SBDC
Bar Code Rule			2					
Future of Healthcare Study						2		
Health IT	2		2		2	2		
Labor / Card Check	2		2					
Patient Privacy/HIPAA	2	2	2		2			

Long Term Consideration

	Date Added	Notes
Consolidation	4/6/2007	
Future of Pharmacy (Pharmacy 2020)	4/6/2007	
Health IT	4/6/2007	
International Distribution	4/6/2007	
Risk Management	4/6/2007	
Sustainability/Corporate Social Responsibility	8/10/2007	
Vertical Integration	4/6/2007	

Removed

	Date Removed	Reason
856 Ship Notice w/ Healthcare Product Data	2/3/2011	Contained in EDI and Healthcare Standards
1099 Reporting	8/1/2011	Issue resolved
BioShield Reauthorization	2/7/2007	Issue resolved
Data Management Study	2/3/2011	Contained in Healthcare Stds and Pedigree
DEA CSOS: EDI Guidelines	4/6/2007	All related issues now under DEA CSOS
DEA Fees	4/6/2007	Combined with DEA Rules
DME Accreditation / Surety Bond	9/15/2010	
DOD - Tricare	2/7/2007	Issue resolved
Generic Drugs: EPC / RFID Cost-Benefit	4/6/2007	Contained under Rx SafeTrack
Generic Drugs: Settlements/Reimbursement	4/6/2007	Combined under Generic Drug Issues
Healthcare Reform (non-HDMA priorities)	1/28/2011	Bill signed into law in 2010
Medicare Part D / Price Negotiation / Other	9/15/2010	
PDMA Regulations and Requirements	2/7/2007	Combined with Pedigree Requirements
PDUFA (Rx Manufacturer User Fees)	7/2/2007	
Repackaging	2/7/2007	Combined with NDC Rule
Rx SafeTrack	1/28/2011	Formal effort no longer operating
State Bulk Purchasing	8/1/2008	No state activity
Thymerisol	7/2/2007	
Track & Trace Standards	2/7/2007	Combined into EPC Standards

STATUS: 1 = Active Project or Issue; 2 = Monitoring / Emerging
PRIORITY: A = High for organization and/OR industry; B = Medium; C = Low

Case: 1:17-md-02804-DAP Doc #: 3003-8 Filed: 12/17/19 37 of 66. PageID #: 432855

ABDCMDL00284795

PROPOSED DASHBOARD CHANGES

"A" Priorities

Federal Government Affairs (FGA)

- MODIFY (from B1 to A2) Rx Waste/Disposal *add* "/Take Back" (To read: Rx Waste/Disposal/Take-Back)
  - As DEA moves forward with implementing regulations on Controlled Substance Disposal, there may be a need to engage with Congressional sponsors of original legislation to address discrepancies between the intent of the legislation and the proposed rule.

State Government Affairs (SGA)

- MODIFY (from B1 to A2) Rx Waste/Disposal/Take-Back
  - With above mentioned activity and pending litigation in the Alameda Country (CA) drug take-back ordinance this issue is likely to become more active at the state level.

Regulatory Affairs (Reg)

- MODIFY (from B1 to A1) Rx Waste/Disposal/Take-Back
  - DEA proposed rule on Controlled Substance Disposal will require significant effort on behalf of regulatory affairs department/staff. EPA and DOT also considering new/revised waste regulations.

Industry Relations (IR)

- MODIFY (from B2 to A2) Rx Waste/Disposal /Take-Back
  - Given the increasing legislative and regulatory activity on this issue there should be a corresponding elevation in priority of this issue for the Industry Relations Department

"B" Priorities

- NO CHANGES

"C" Priorities

- NO CHANGES

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GARY M. ZIZKA

MEMORANDUM

January 7, 2013

BY ELECTRONIC MAIL

TO: Health Distribution Management Association

FROM: Olsson Frank Weeda Terman Matz PC

RE: Summary of DEA Proposed Rulemaking Under the Secure and Responsible Drug Disposal Act of 2010

On December 21, 2012, the Drug Enforcement Administration ("DEA") issued a notice of proposed rulemaking to modify and expand the options available to collect controlled substances from ultimate users for the purpose of disposal and to amend the requirements for the secure disposal of controlled substances by DEA registrants and ultimate users. 77 Fed. Reg. 75,784 (December 21, 2012) ("Proposed Rule") (copy attached).

This Memorandum is limited to a general overview of the Proposed Rule with a focus on provisions relevant to distributors and reverse distributors. **Comments to the Proposed Rule are due on or before February 19, 2013**.

1. SUMMARY

The Proposed Rule is intended to implement the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act") (Pub. L. No. 111–273) which, in turn, amends the Controlled Substance Act ("CSA"), 21 U.S.C. §§ 801 *et seq.* The Disposal Act allows an ultimate user – the patient – to deliver a controlled substance "to another person for the purpose of disposal." 21 U.S.C. § 822(g)(1).

The provisions of the Proposed Rule that would implement "take-back" programs to collect controlled substances from ultimate users are voluntary. DEA proposes various collection, security, and recordkeeping requirements for those entities that chose to participate.

We caution, however, that the Proposed Rule reaches far beyond the establishment of parameters for voluntary collection programs to manage controlled substances returned from ultimate users. The Proposed Rule addresses more broadly the traditional movement of all controlled substances back through the closed supply chain, among and between DEA registrants, for return, recall, disposal, and destruction. DEA proposes to delete the current disposal, recall, and return regulations in 21 C.F.R. § 1307.21 and § 1307.12 and proposes a new part 1317. Interest in several states could result in states mandating "take-back" programs based upon this DEA model, should the proposal be promulgated as a final rule.

Below, we summarize those provisions of the Proposed Rule that, if finalized, *would affect both distributors and reverse distributors specifically*:

- The establishment of a voluntary collection program for the return, accounting for, and destruction of controlled substances from ultimate users and the attendant security and recordkeeping requirements associated with participation in such a program.
- Requirements for the disposal and destruction of all controlled substances, whether as part of a collection program or received as a return or recall in the normal course of business.
- Requirements regarding controlled substance recalls and returns.

Other provisions of the Proposed Rule are specific to reverse distributors alone and are addressed in a separate summary.

We encourage members especially to review closely the new, proposed 21 C.F.R. Part 1317, 77 Fed. Reg. at 75,811-17.

2. COLLECTING CONTROLLED SUBSTANCES FROM ULTIMATE USERS – TAKE-BACK PROGRAMS, MAIL-BACK PROGRAMS AND COLLECTION RECEPTACLES

a. Collectors

- The Proposed Rule creates a new sub-category of existing, authorized registrants known as "collectors." "Collector" is defined in proposed 21 C.F.R. § 1300.01(b) as a registered manufacturer, distributor, reverse distributor, or retail pharmacy that is authorized to receive a controlled substance from an ultimate user.[1]

[1] 77 Fed. Reg. at 75,808, proposed 21 C.F.R. § 1301.01.

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- To become a collector, a manufacturer, distributor, reverse distributor, or retail pharmacy would have to submit a letter request to DEA to modify its existing registration.[2]

- Authorized collectors may receive controlled substances from (1) an "ultimate user"[3]; (2) persons lawfully entitled to dispose of an ultimate user decedent's property and (3) a Long Term Care Facility ("LTCF") on behalf of ultimate users that reside or have resided in that LTCF.[4] (These three categories are referred to collectively as "ultimate users.")

b. Authorized Collector Collection And Disposal Of Controlled Substances

- Distributors and reverse distributors may amend their existing DEA registrations to become authorized collectors.[5]

- DEA proposes three voluntary options for ultimate users to dispose of controlled substances:

  - take-back events where an ultimate user delivers controlled substances to law enforcement;

  - mail-back programs where an ultimate user mails controlled substances in postage prepaid envelopes to an authorized collector's registered location for destruction at that site; and

  - collection receptacles where an ultimate user places controlled substances in a lined, secure receptacle at a registered location of an authorized collector and the collector periodically arranges for the receptacle's secure inner liner to be removed and transported to ensure for destruction.[6]

- Only retail pharmacies would be permitted to operate collection receptacles in LTCFs.[7]

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[2] 77 Fed. Reg. at 75,809, proposed 21 C.F.R. § 1301.51.

[3] The CSA defines an "ultimate user" as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household." 21 U.S.C. § 802(27).

[4] 77 Fed. Reg. at 75,808, proposed 21 C.F.R. § 1300.01. It is unclear how a retail pharmacy's registration, which is tied to its location, would extend to a collection receptacle in an LTCF at another location.

[5] 77 Fed. Reg. at 75,808, proposed 21 C.F.R. § 1301.01.

[6] 77 Fed. Reg. at 75,790, col 2.

[7] 77 Fed. Reg. at 75,814, proposed 21 C.F.R. § 1317.40(b)(2).

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- DEA proposes numerous security, recordkeeping, and physical requirements for authorized collectors, including inventory and tracking controls on their mail-back envelopes and the removable inner liners of drug collection receptacles and the placement, construction, and monitoring of collection receptacles as well as storage and disposal of collected controlled substances.[8] Authorized collectors would be required to destroy promptly product received from mail-back programs[9] and in inner liners from collection receptacles;[10] if not destroyed promptly,[11] the mail-back packages and inner liners would have to be stored as if they contained Schedule II controlled substances. The regulations would permit the comingling of controlled and non-controlled substances and exempt authorized collectors from ARCOS and order form reporting. [12]

c. Distributor and Reverse Distributor Receipt Of Collected Controlled Substances (When Not An Authorized Collector)

- Distributors and reverse distributors would be permitted to acquire controlled substances from law enforcement agencies or authorized collectors such as pharmacies without amending their registrations to become authorized collectors because the drugs received are already securely sealed in a mail-back package received from law enforcement or a sealed inner liner.[13]

- Both distributors and reverse distributors would be able to acquire controlled substances from authorized collectors such as pharmacies that collect controlled substances through a collection receptacle. [14]

- Reverse distributors would be able to acquire controlled substances from law enforcement, including mail-back envelopes sent to law enforcement.[15]

- Upon receipt of the collected controlled substances, the distributor or reverse distributor would be required to:

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[8] 77 Fed. Reg. at 75,814-15, proposed 21 C.F.R. § 1317.45, § 1317.50. *See also* 77 Fed. Reg. at 75,815-16, proposed 21 C.F.R. § 1317.60 - § 1317.75 (regulations specific to take-back events, collection receptacles, and mail-back programs).

[9] If a pharmacy, distributor, or reverse distributor becomes an authorized collector conducting a mail-back program, it must have the packages delivered directly to the site where the envelope will be destroyed; mail-back packages may not be transferred between locations. 77 Fed. Reg. at 75,794, col. 3.

[10] 77 Fed. Reg. at 75,812, proposed 21 C.F.R. § 1317.05(c)(1)(i), (c)(2)(i).

[11] Reverse distributors who are authorized collectors would have to dispose of collected product within fourteen days of receipt. 77 Fed. Reg. at 75,795, col. 3.

[12] 77 Fed. Reg. at 75,815, proposed 21 C.F.R. § 1317.50(c)-(d).

[13] 77 Fed. Reg. at 75,793, col 2-3.

[14] 77 Fed. Reg. at 75,815, proposed 21 C.F.R. § 1317.55.

[15] 77 Fed. Reg. at 75,815, proposed 21 C.F.R. § 1317.55.

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- *Immediately* and securely store the mail-back envelope or inner liner at the reverse distributor's registered location until timely destruction (or transfer the controlled substance to the reverse distributor's registered location for secure storage and timely destruction); or

- *Immediately* deliver the controlled substance to the location of destruction for timely destruction.[16]

- Destroy or cause the destruction, as soon as practicable but *no later than fourteen calendar days* of receipt.[17]

- Controlled substances reverse distributors and distributors received from law enforcement and authorized collectors:

  - Could be comingled with non-controlled substances.[18]

  - Could be destroyed in the mail-back envelopes or inner liner in which they were received. This means that reverse distributors and distributors could not and, in fact, *must not open* mail-back envelopes received from law enforcement or inner liners received from authorized collectors to individually count or inventory the drugs contained within.[19]

  - Would not be subject to ARCOS reporting or order forms.[20]

- A reverse distributor or distributor that acquires controlled substances from authorized collectors or law enforcement must maintain the following records:

  - Upon receipt: The date of receipt; the name and address of the law enforcement agency or the name, address, and DEA registration number of the authorized collector from whom the inner liner (or mail-back package if from a law enforcement agency) was received; the unique identification number of the inner liner or mail-back package; and the size of the inner liner.

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[16] 77 Fed. Reg. at 75,815, proposed 21 C.F.R. § 1317.55(c)(2)(i)-(ii). There are separate disposal and handling requirements for controlled substances received by authorized collectors, 77 Fed. Reg. at 75,812, proposed 21 C.F.R. § 1317.05(c). Distributors and reverse distributors do not need to be authorized collectors, 77 Fed. Reg. at 75,793, col. 2-3, to receive controlled substances.

[17] 77 Fed. Reg. at 75,815, proposed 21 C.F.R. § 1317.55(c)(2)(iii).

[18] 77 Fed. Reg. at 75,816, proposed 21 C.F.R. § 1317.65(d), § 1317.70(b), § 1317.75(d).

[19] 77 Fed. Reg. at 75,793, col. 1; 77 Fed. Reg. at 75,81, proposed 21 C.F.R. § 1317.70(f), § 1317.75(g).

[20] 77 Fed. Reg. at 75,815, proposed 21 C.F.R. § 1317.55(e)-(f).

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- Upon transfer to secure storage: The date of storage; the address and DEA number of the storage location; the unique identification number of the inner liner or mail-back package; and the size of the inner liner.[21]

- Because sealed liners and mail-back envelopes cannot be opened, it must assumed that they contain controlled substances and so, if not destroyed immediately, they would have to be stored consistent with the requirements for storage of Schedule II controlled substances until timely destruction can occur.[22]

3. REGISTRANT DISPOSAL OF CONTROLLED SUBSTANCES

DEA proposes a "non-retrievable" standard for destruction of controlled substances. The proposed definition of "non-retrievable" means to permanently alter any controlled substance's physical and/or chemical state through irreversible means to render that controlled substance unavailable and unusable for all practical purposes.[23] Examples of current technology that may achieve non-retrievable destruction include incineration and chemical digestion.[24] DEA solicits comments on what would constitute "non-retrievable."[25]

a. Destruction Procedures

Under the Proposed Rule, non-practitioner registrants, including distributors and reverse distributors, would dispose of controlled substances *in inventory* using one of the following methods:

- Promptly destroy the substance using an on-site method of destruction in accordance with applicable federal, state, tribal, and local laws and regulations that renders the controlled substance non-retrievable;

- Promptly deliver the substance to a reverse distributor at its registered location by common or contract carrier, or by reverse distributor pick-up;

- In the event of a product return or recall, promptly deliver the substance by common or contract carrier or pick-up to the person from whom it was obtained, the manufacturer, or another registrant the manufacturer authorizes; or

[21] 77 Fed. Reg. at 75,815, proposed 21 C.F.R. § 1317.55(d).

[22] 77 Fed. Reg. at 75,815, proposed 21 C.F.R. § 1317.55(c)(3).

[23] 77 Fed. Reg. at 75,803, col. 3; 77 Fed. Reg. at 75,808, proposed 21 C.F.R. § 1300.01

[24] 77 Fed. Reg. at 75,803, col. 3.

[25] 77 Fed. Reg. at 75,803, col. 3.

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- Promptly transport the substance by its own means to a reverse distributor, the location of destruction, or the registered location of any person authorized to receive the substance for the purpose of return or recall.[26]

These disposal requirements for a registrant's controlled substances *in inventory* would be distinct from the distributor or reverse distributor's disposal of *collected* controlled substances which is described in section 2 above.

For *all* registrants that destroy *any* controlled substances (whether collected or in inventory), DEA proposes additional security measures, including:

- Two authorized employees would have to load and unload controlled substances (or observe the same) during transfer of the substances to another registrant, such as the manufacturer or reverse distributor; and

- If the substances are destroyed on a registrant's registered premises, two authorized employees would have to personally witness the destruction.[27]

b. <u>Recordkeeping For Disposals/Destructions</u>

- Registrants that cause destruction of controlled substances would be required to complete a Form DEA 41 which will be modified to be a record of destruction. Registrants would no longer be required to submit three copies to DEA, but would be required to maintain the form for two years as a record to be available for inspection. [28]

- Any registered person that destroys or causes the destruction of a controlled substance shall maintain the following records of the destruction:
    - The date of destruction;
    - The method of destruction;
    - The name and address of the place of destruction;
    - The name and *quantity* of the controlled substances destroyed (or the unique identification number of the inner liner or mail-back package destroyed if the substances received from law enforcement or authorized collectors as described in section 2 above); The size of the inner liner destroyed; and

[26] 77 Fed. Reg. at 75,812, proposed 21 C.F.R. § 1317.05(b).

[27] 77 Fed. Reg. at 75817, proposed 21 C.F.R. § 1317.95.

[28] 77 Fed. Reg. at 72,807.

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- The name and signature of the two authorized employees who witnessed the destruction.[29]

- If the controlled substances destroyed were received from another registrant, the registrant destroying the controlled substances shall maintain a copy of the record transferring the substances or a copy of the Form DEA 222.[30]

4. RETURN AND RECALL

The Proposed Rule deletes the current procedures on returns and recalls, 21 C.F.R. 1307.12, while maintaining many relevant parts in a proposed new 21 C.F.R. § 1317.10 and § 1317.85.

The Proposed Rule would, if finalized, allow registrants in lawful possession of a controlled substance to return that substance for the purpose of return or recall to:

- The registered person from whom it was obtained;

- The registered manufacturer of the substance; or

- Another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf.[31]

Proposed 21 C.F.R. § 1317.10(a) would require all registrants to maintain certain records of returns and recalls of controlled substances. Distributor recordkeeping is currently set out in 21 C.F.R. § 1304.22(b). For each controlled substance a registrant, including a distributor or reverse distributor, received would be required to maintain the following in a recall or for a return: the date of the transaction; the name, form, and quantity of each controlled substance received; and the name, address, and registration number of the delivering registrant from whom the substance was received.[32] Deliveries may be made through a freight forwarding facility.[33]

Each registrant who delivers a Schedule I or II controlled substance for a return or recall would be required to use a Form DEA 222.[34] Registrants who receive recalled controlled substances from ultimate users are exempt from the Form DEA 222 order form requirement.[35]

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[29] 77 Fed. Reg. at 75,817, proposed 21 C.F.R. § 1317.95.

[30] 77 Fed. Reg. at 75,817, proposed 21 C.F.R. § 1317.100.

[31] 77 Fed. Reg. at 75,811, proposed 21 C.F.R. § 1317.05(a)(3); 77 Fed. Reg. at 75,812, proposed § 1317.05(b)(3).

[32] 77 Fed. Reg. at 75,812, proposed 21 C.F.R. § 1317.10(a)(2). *See also* 77 Fed. Reg. at 75,817, proposed 21 C.F.R. § 1317.85(a)(1).

[33] 77 Fed. Reg. at 75,812, proposed 21 C.F.R. § 1317.10(c).

[34] 77 Fed. Reg. at 75,812, proposed 21 C.F.R. § 1317.10(b).

[35] 77 Fed. Reg. at 75,817, proposed 21 C.F.R. § 1317.85(a)(2).

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For purposes of ARCOS reporting, a registrant accepting recalled controlled substances may report as a single transaction all recalled controlled substances of the same name and finished form (e.g., all 10-mg tablets, all 5-mg concentration per mL) received from ultimate users.[36]

5. NEW "AUTHORIZED EMPLOYEE" AND EMPLOYEE SECURITY REQUIREMENTS

DEA also inserted, without direction under the Secure and Responsible Drug Disposal Act, a new definition and security requirement regarding employees. In the definitional section of proposed Part 1317, DEA proposes the following new definition of "Authorized Employee."

> *Authorized Employee* means an individual employed full time by the registrant, who has not been convicted of a felony offense related to controlled substances and has not, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause.[37]

Then in proposed section 1317.20, DEA inserts an additional employee security requirement:

> A registered reverse distributor shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.[38]

This provision is not parallel to the ordinary employee screening provisions of 21 C.F.R. § 1301.90, applicable to all other non-practitioners. It imposes a new regulatory requirement. It is unclear, and should be considered for comment, whether the scope of this proposed prohibition includes anyone who has ever worked for a registrant that had a DEA registration revoked, suspended or surrendered "for cause"[39] or whether it applies only to principals of a registrant that had a DEA registration revoked, suspended or surrendered. This could have implications for any HDMA member that has ever had a facility subject to an Order of Immediate Suspension/Order To Show Cause, as well as the employees that worked at such facilities.

* * * * *

[36] 77 Fed. Reg. at 75,817, proposed 21 C.F.R. § 1317.85(a)(3).

[37] 77 Fed. Reg. at 75,811, proposed 21 C.F.R. § 1317.02(a).

[38] 77 Fed. Reg. at 75,813, proposed 21 C.F.R. § 1317.20.

[39] The definition of "for cause" is proposed at 77 Fed. Reg. at 75,811. "*For cause* means in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances."

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OFW LAW
OLSSON FRANK WEEDA TERMAN MATZ PC

We trust you will find this information useful, and we would be pleased to discuss it and consideration of comments further, as you deem appropriate.

OFW:lav
Attachment

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February 1, 2013

Douglas C. Throckmorton, M.D.
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Drug Safety and Risk Management Advisory Committee; Notice of Meeting Docket No. FDA-2012-N-0548 (77 Fed. Reg. 34051, June 8, 2012; 77 Fed. Reg. 75176, December 19, 2012)

Dear Dr. Throckmorton:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide our views on the Food and Drug Administration's (FDA) analysis of the factors associated with determining whether to move hydrocodone combination products from their current placement in Schedule III to Schedule II under the Controlled Substances Act (CSA).

HDMA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that nine million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated $42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.

HDMA acknowledges that there is a prescription drug abuse problem in the United States and agrees that more must be done to improve understanding about the addictive nature of prescription pain medicines and to help prevent diversion. HDMA also commends the Agency, the Drug Safety and Risk Management Advisory Committee, the Drug Enforcement Administration (DEA), and the multiple other stakeholders concerned for the safety of the drugs and the patients who need them for seeking effective solutions to a complex problem. Similarly, we are committed to working collaboratively with federal, state and local officials, as well as our colleagues in the pharmaceutical supply chain to help prevent diversion and the inappropriate use of these products. We also share concerns that there continue to be access to these important products for those with legitimate medical needs.

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To that end, HDMA has worked to help meet this public health challenge by participating in educational, outreach and other programs. HDMA members go to great lengths to provide the safest, most secure distribution network in the world. Further, behind the scenes, they have exerted tremendous efforts to develop extensive and highly sophisticated monitoring systems. Keeping in mind that wholesale distributors do not see, prescribe for, dispense to, or sell controlled substances to patients, distributors have focused upon providing a greater level of assurance that the healthcare entities that purchase controlled substances from distributors do so with the intention to administer or dispense them for appropriate purposes.

HDMA understands that FDA's primary consideration in making a scheduling decision will be the impacts on patients and the eight factors outlined in the CSA. However, if hydrocodone combination products are designated as Schedule II drugs, such "upscheduling" will result in significant additional security and ordering requirements in an already very secure environment. Unfortunately, these additional requirements will do nothing to prevent the types of non-medical abuses most often associated with hydrocodone combination drugs.

Thus, as FDA evaluates hydrocodone combination products for addictive properties and the public health implications of a rescheduling decision, we urge the agency to consider the following:

1. Include a description of the impacts on logistics and the supply chain as part of the final recommendation submitted to the DEA. While such impacts may not be as directly associated with patient care as other factors, they do exist and have serious, adverse effects upon legitimate patient treatment and access.

2. If FDA concludes that a recommendation to reassign these products to Schedule II is appropriate, consider including a clarification within the recommendation, that the decision was based on patient utilization and these products' addictive properties, not on facility security considerations.

3. Given the potential impacts on logistical changes resulting from rescheduling these products could have on supply, also recommend that DEA consider applying the security controls of 21 C.F.R. § 1301.72(b) to hydrocodone combination products in lieu of 21 C.F.R. § 1301.72(a) if they are reassigned to Schedule II. These provisions will not aid in preventing the means by which most of those using these products for non-medical purposes obtain them. This step would be consistent with that of other decision-makers, such as New York state which established a precedent for such an exemption by allowing "*…manufacturers and distributors [to treat them] as if such substances were set forth in Schedule III…*"[1] in the state's recently enacted legislation designed to help curb drug abuse. This step would not result in harm to either patients or security and would resolve

[1] NYA10623. See also: http://www.governor.ny.gov/press/06052012prescription-drugs

potential concerns about an unavoidable multi-year time frame for implementing a schedule change due to the limited design/construction firm expertise available to build vaults to specifications.

4. We urge continued exploration and development of the many alternative options for moderating the non-medical use, and abuse, of prescription drugs.

5. HDMA requests the opportunity to meet with the agency to discuss our views further, prior to reaching a final decision on rescheduling.

CONCLUSION

The attachment to this letter provides further detail on the potential impacts. We hope this information will provide additional factors to consider during the agency's deliberations.

HDMA thanks FDA for this opportunity to comment and we look forward to further interaction on this topic. If you have any questions, or if HDMA can provide further information, please do not hesitate to contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,

Anita T. Ducca
Vice President, Regulatory Affairs

Attachment

Congress of the United States
Washington, DC 20515

January 28, 2013

The Honorable Margaret Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

We are writing to urge you to adopt last week's recommendation of your expert advisory panel to place tighter restrictions on prescription painkillers that use the active ingredient hydrocodone. This change mirrors legislation we introduced in the last Congress to reschedule hydrocodone combination drugs from a Schedule III to a Schedule II drug. We intend to re-introduce this bipartisan legislation later this week.

Prescription drug abuse is wreaking havoc on countless families and communities across our nation. This epidemic has reached such disastrous proportions that fatal drug overdoses now outnumber the total amount of traffic fatalities in this country. Products containing hydrocodone, such as Vicodin and Lortab, are fueling this epidemic. These drugs are now the most widely prescribed painkillers in the country, with more than 131 million prescriptions for hydrocodone written in 2010 alone. That's enough to give 24 pills to every man, woman and child in the U.S.

Other opioid painkillers, such as OxyContin and Percocet, are made with the active ingredient oxycodone. The Drug Enforcement Agency (DEA) considers these products to have "a high potential for abuse with severe psychological or physical dependence" and thus classifies them as tightly-regulated Schedule II drugs. Hydrocodone products, on the other hand, are currently classified as Schedule III drugs – a category of products that are considered to have a lower potential for abuse than drugs in Schedule II. This reflects the belief among some doctors that hydrocodone combination drugs are less potent or less habit-forming than oxycodone painkiller. As a result, while almost every opioid painkiller is considered a Schedule II drug and thus carefully regulated, America's most abused narcotic is conspicuously missing from this list.

We do not believe that a Schedule III classification – reserved for drugs with a "moderate" potential for abuse – is appropriate for hydrocodone combination drugs. As Dr. Andrew Kolodny, president of Physicians for Responsible Opioid Prescribing, said in a recent interview with CNN, "When you wonder why your dentist gives you 40 hydrocodone for a toothache…that's because they're under the impression that it's not addictive as Percocet. That's completely false."

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We agree, which is why we introduced the *Pill Mill Crackdown Act.* Re-classifying hydrocodone combination drugs would limit how much hydrocodone a patient can receive in between doctor visits and would require written prescriptions, rather than prescriptions that are faxed or called in by phone. Our legislation drew wide support from law enforcement and addiction advocates, including the National District Attorneys Association, the National Criminal Justice Association, and the National Coalition Against Prescription Drug Abuse. It also received bipartisan support from 58 co-sponsors in the House of Representatives.

Re-classification of hydrocodone combination drugs alone is not enough to end the scourge of prescription drug abuse, and we need to ensure that any changes protect the ability of patients with a legitimate medical need to access these medications. But regulating these potent painkillers appropriately is a critical step. We have heard too many stories of a father who started taking painkillers for a bad back only to overdose a few years later, leaving his family behind. We have heard of too many teenagers who failed to grasp the potency of these painkillers and whose lives were cut far too short. Solving this public health crisis will require a massive effort that includes tough law enforcement measures and education for providers and patients about the risks of prescription painkillers. But we should start by recognizing the severe risk of abuse and addiction of these painkillers and by classifying them accordingly.

We urge you to accept your board's recommendation in the name of every family who has endured the horrors of prescription drug abuse, and we thank you for your consideration of our request.

Sincerely,

Vern Buchanan
Member of Congress

Edward J. Markey
Member of Congress

DHCS Proposed draft language for discussion

Changes to current law related to Average Acquisition Cost (AAC) -Quality Assurance Program (QAP)

(Additions denoted by bold underline, deletions denoted by strikethrough)

14105.45. (a) For purposes of this section, the following definitions shall apply:

(1) "Average acquisition cost" means the average weighted cost determined by the department to represent the actual acquisition cost paid for drugs by Medi-Cal pharmacy providers, including those that provide specialty drugs. The average acquisition cost shall not be considered confidential and shall be subject to disclosure pursuant to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(2) "Average manufacturers price" means the price reported to the department by the federal Centers for Medicare and Medicaid Services pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8).

(3) "Average wholesale price" means the price for a drug product listed as the average wholesale price in the department's primary price reference source.

(4) "Estimated acquisition cost" means the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package.

(5) "Federal upper limit" means the maximum per unit reimbursement when established by the federal Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

(6) "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength and dosage form, and of the same generic drug name, as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

(7) "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(8) "Maximum allowable ingredient cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

(9) "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code.

(10) "Nonlegend drug" means any drug whose labeling does not contain the statement referenced in paragraph (7).

(11) "Pharmacy warehouse," as defined in Section 4163 of the Business and Professions Code, means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

(12) "Specialty drugs" means drugs determined by the department pursuant to subdivision (f) of Section 14105.3 to generally require special handling, complex dosing regimens, specialized self-administration at home by a beneficiary or caregiver, or specialized nursing facility services, or may include extended

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patient education, counseling, monitoring, or clinical support.
(13) "Volume weighted average" means the aggregated average volume for a group of legend or nonlegend drugs, weighted by each drug's percentage of the group's total volume in the Medi-Cal fee-for-service program during the previous six months. For purposes of this paragraph, volume is based on the standard billing unit used for the legend or nonlegend drugs.
(14) "Wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail pharmacies in California.
(15) "Wholesaler acquisition cost" means the price for a drug product listed as the wholesaler acquisition cost in the department's primary price reference source.
(16) "Manufacturer" means a manufacturer as defined in Section 1396r-8(k)(5) of Title 42 of the United States Code.

(17) "AAC quality assurance program"means the independent verification and validation oversight functions the Department shall perform to ensure the integrity of the Average Acquisition Cost Pharmacy Reimbursement Methodology and that it continues to accurately reflect actual drug product acquisition costs paid by Medi-Cal Pharmacy providers to Manufacturers, Wholesalers and Pharmacy warehouses.

(b) (1) Reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs shall not exceed the lowest of either of the following:
(A) The estimated acquisition cost of the drug plus a professional fee for dispensing.
(B) The pharmacy's usual and customary charge as defined in Section 14105.455.
(2) The professional fee shall be seven dollars and twenty-five cents ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility shall be eight dollars ($8) per dispensed prescription. For purposes of this paragraph "skilled nursing facility" and "intermediate care facility" shall have the same meaning as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations. If the department determines that a change in dispensing fee is necessary pursuant to this section, the department shall establish the new dispensing fee through the budget process and implement the new dispensing fee pursuant to subdivision (d).
(3) The department shall establish the estimated acquisition cost of legend and nonlegend drugs as follows:
(A) For single source and innovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the average acquisition cost, the federal upper limit, or the MAIC.
(B) For noninnovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the average acquisition cost, the federal upper limit, or the MAIC.
(C) Average wholesale price shall not be used to establish the estimated acquisition cost once the department has determined that the average acquisition cost methodology has been fully implemented.
(4) For purposes of paragraph (3), the department shall establish

a list of MAICs for generically equivalent drugs, which shall be published in pharmacy provider bulletins and manuals. The department shall establish a MAIC only when three or more generically equivalent drugs are available for purchase and dispensing by retail pharmacies in California. The department shall update the list of MAICs and establish additional MAICs in accordance with all of the following:

(A) The department shall base the MAIC on the mean of the average manufacturer's price of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

(B) If average manufacturer prices are unavailable, the department shall establish the MAIC in one of the following ways:

(i) Based on the volume weighted average of wholesaler acquisition costs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

(ii) Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.

(iii) Based on the volume weighted average acquisition cost of drugs generically equivalent to the particular innovator drug adjusted by the department to represent the average purchase price paid by Medi-Cal pharmacy providers.

(C) The department shall update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

(D) The department shall establish a process for providers to seek a change to a specific MAIC when the providers believe the MAIC does not reflect current available market prices. If the department determines a MAIC change is warranted, the department may update a specific MAIC prior to notifying providers.

(E) In determining the average purchase price, the department shall consider the provider-related costs of the products that include, but are not limited to, shipping, handling, storage, and delivery. Costs of the provider that are included in the costs of the dispensing shall not be used to determine the average purchase price.

(5) (A) The department may establish the average acquisition cost in one of the following ways:

(i) Based on the volume weighted average acquisition cost adjusted by the department to ensure that the average acquisition cost represents the average purchase price paid by retail pharmacies in California.

(ii) Based on the proposed average acquisition cost as calculated by the vendor pursuant to subparagraph (B).

(iii) Based on a national pricing benchmark obtained from the federal Centers for Medicare and Medicaid Services or on a similar benchmark listed in the department's primary price reference source adjusted by the department to ensure that the average acquisition cost represents the average purchase price paid by retail pharmacies in California.

(B) For the purposes of paragraph (3), the department may contract with a vendor for the purposes of surveying drug price information,

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collecting data from providers, wholesalers, or drug manufacturers, and calculating a proposed average acquisition cost.

(C) (i) Medi-Cal pharmacy providers shall submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost. The information submitted by pharmacy providers shall include, but not be limited to, invoice prices and all discounts, rebates, and refunds known to the provider that would apply to the acquisition cost of the drug products purchased during the calendar quarter. Pharmacy warehouses shall be exempt from the survey process, but shall provide drug cost information upon audit by the department for the purposes of validating individual pharmacy provider acquisition costs.

(ii) Pharmacy providers that fail to submit drug price information to the department or the vendor as required by this subparagraph shall receive notice that if they do not provide the required information within five working days, they shall be subject to suspension under subdivisions (a) and (c) of Section 14123.

(D) ~~(i) For new drugs or new formulations of existing drugs, where drug price information is unavailable pursuant to clause (i) of subparagraph (C), drug manufacturers and wholesalers shall submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost. Drug price information shall include, but not be limited to, net unit sales of a drug product sold to retail pharmacies in California divided by the total number of units of the drug sold by the manufacturer or wholesaler in a specified period of time determined by the department.~~

~~(ii) Drug products from manufacturers and wholesalers that fail to submit drug price information to the department or the vendor as required by this subparagraph may not be a reimbursable benefit of the Medi-Cal program. for those manufacturers and wholesalers until the department has established the average acquisition cost for those drug products.~~

~~(E) Drug pricing information provided to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).~~

(F) Prior to the implementation of an average acquisition cost methodology, the department shall collect data through a survey of pharmacy providers for purposes of establishing a professional fee for dispensing in compliance with federal Medicaid requirements.

(i) The department shall seek stakeholder input on the retail pharmacy factors and elements used for the pharmacy survey relative to both average acquisition costs and dispensing costs. Any adjustment to the dispensing fee shall not exceed the aggregate savings associated with the implementation of the average acquisition cost methodology.

(ii) For drug products provided by pharmacy providers pursuant to subdivision (f) of Section 14105.3, a differential professional fee or payment for services to provide specialized care may be considered as part of the contracts established pursuant to that section.

(G) When the department implements the average acquisition cost methodology, the department shall update the Medi-Cal claims processing system to reflect the average acquisition cost of drugs

not later than 30 days after the department has established average acquisition cost pursuant to subparagraph (A).

(H) Notwithstanding any other provision of law, if the department implements average acquisition cost pursuant to clause (i) or (ii) of subparagraph (A), the department shall update actual acquisition costs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of any change in an actual acquisition cost.

(I) The department shall establish a process for providers to seek a change to a specific average acquisition cost when the providers believe the average acquisition cost does not reflect current available market prices. If the department determines an average acquisition cost change is warranted, the department may update a specific average acquisition cost prior to notifying providers.

(c)The department shall establish an AAC quality assurance program.

(i) Manufacturers, Wholesalers and Pharmacy Warehouses shall provide information and documentation to the department for the purposes of performing AAC quality assurance program functions.

(ii) The department shall submit a report on the AAC quality assurance program to the appropriate fiscal and policy committees of the Legislature no later than 5 years after the AAC program is fully implemented. The report shall provide information on the AAC program quality, integrity, risks, vulnerabilities and specific program measures that are utilized to consistently monitor the AAC pharmacy program ensuring compliance with applicable State and Federal laws.

(d) Information and documentation provided to the department for the purposes of establishing acquisition cost or for performing AAC quality assurance program functions pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

~~(c)~~ **(e)** The director shall implement this section in a manner that is consistent with federal Medicaid law and regulations. The director shall seek any necessary federal approvals for the implementation of this section. This section shall be implemented only to the extent that federal approval is obtained.

~~(d)~~**(f)** Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

~~(e)~~**(g)** The department may enter into contracts with a vendor for the purposes of implementing this section on a bid or nonbid basis. In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into to implement this section, and all contract amendments and change orders, shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

~~(f)~~**(h)** (1) The rates provided for in this section shall be implemented only if the director determines that the rates will comply with applicable federal Medicaid requirements and that federal financial participation will be available.

(2) In determining whether federal financial participation is

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available, the director shall determine whether the rates comply with applicable federal Medicaid requirements, including those set forth in Section 1396a(a)(30)(A) of Title 42 of the United States Code.

(3) To the extent that the director determines that the rates do not comply with applicable federal Medicaid requirements or that federal financial participation is not available with respect to any rate of reimbursement described in this section, the director retains the discretion not to implement that rate and may revise the rate as necessary to comply with federal Medicaid requirements.

~~(g)~~ **(i)** The director shall seek any necessary federal approvals for the implementation of this section.

~~(h)~~ **(j)** This section shall not be construed to require the department to collect cost data, to conduct cost studies, or to set or adjust a rate of reimbursement based on cost data that has been collected.

~~(i)~~ **(k)** Adjustments to pharmacy drug product payment pursuant to Section 14105.192 shall no longer apply when the department determines that the average acquisition cost methodology has been fully implemented and the department's pharmacy budget reduction targets, consistent with payment reduction levels pursuant to Section 14105.192, have been met.

~~(j)~~ **(l)** Prior to implementation of this section, the department shall provide the appropriate fiscal and policy committees of the Legislature with information on the department's plan for implementation of the average acquisition cost methodology pursuant to this section.

14105.451. (a) (1) The Legislature finds and declares all of the following:

(A) The United States Department of Health and Human Services has identified the critical need for state Medicaid agencies to establish pharmacy reimbursement rates based on a pricing benchmark that reflects actual acquisition costs.

(B) The Medi-Cal program currently uses a methodology based on average wholesale price (AWP).

(C) Investigations by the federal Office of Inspector General have found that average wholesale price is inflated relative to average acquisition cost.

(2) Therefore, it is the intent of the Legislature to enact legislation by August 1, 2011, that provides for development of a new reimbursement methodology that will enable the department to achieve savings while continuing to reimburse pharmacy providers in compliance with federal law.

(b) Subject to Section 14105.45, the department may require providers, manufacturers, and wholesalers to submit any data the director determines necessary or useful in preparing for the transition from a methodology based on average wholesale price to a methodology based on actual acquisition cost.

(c) If the AWP ceases to be listed by the department's primary price reference source vendor, the department may direct the fiscal intermediary to establish a process with the primary price reference source vendor to temporarily report the AWP consistent with the definition of AWP in Section 14105.45. If this process is established, it shall be limited in scope and duration, and shall cease when the department has fully implemented the average acquisition cost methodology pursuant to Section 14105.45.

Trade Agreements Act

There are no written materials for this section

Update on Federal Pedigree Activities

There are no written materials for this section

ASP/Prompt Pay Discount

There are no written materials for this section

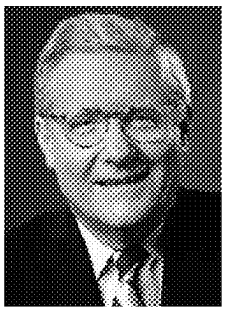
Daniel Todd

Dan Todd is a Health Policy Advisor on the Republican staff of the Senate Finance Committee. His areas of responsibility for the Committee include the Medicare Part B program and the Prescription Drug Benefit (Part D). Prior to joining the Finance Committee, Dan was the Senior Director for Health Policy at EMD Serono, an affiliate of Merck KGaA, Darmstadt, Germany. In this role he provided policy expertise and analysis to senior executives in the company, and represented the company with major trade associations such as PhRMA and BIO. As part of the Government Affairs team, Dan also represented EMD Serono to key state and federal agencies on policy issues.

Prior to his work with EMD Serono, Dan was a Director in Amgen's coverage and reimbursement policy office, with primary responsibility for federal coverage and reimbursement issues for Amgen's oncology portfolio.

Before moving to the private sector, Dan worked as a Special Assistant in the Office of the Administrator at the Centers for Medicare and Medicaid Services (CMS), the federal agency charged with the operation of the Medicare and Medicaid programs. Dan worked on Medicare Part B and Part D issues during the implementation of the Medicare Modernization Act from 2003-2005.

Dan has a B.A. from Georgetown University and a J.D. from The Catholic University of America.



Fred Barnes

Executive Editor, *The Weekly Standard* and Commentator, FOX News

The Political Landscape in Washington

Fred Barnes presentation offers an insider's look at the presidency and Congress. With over 25 years of reporting on Washington politics, his analysis and predictions are among the most on-target of anyone covering Washington. Barnes takes a hard look at the impact of a divided Congress on the Obama agenda for a second term and what issues are front of mind for the American electorate.

About the Speaker

Fred Barnes is co-founder and executive editor of *The Weekly Standard*. From 1985 to 1995, he served as senior editor and White House correspondent for *The New Republic*. He covered the Supreme Court and the White House for the *Washington Star* before moving on to the *Baltimore Sun* in 1979. He served as the national political correspondent for the *Sun* and wrote the "Presswatch" media column for the *American Spectator*.

From 1998 to 2009, he was host, along with Mort Kondracke, of the *Beltway Boys* on FOX News. Barnes appears regularly on FOX's *Special Report with Bret Baier*. From 1988 to 1998, he was a regular panelist on *The McLaughlin Group*. He has also appeared on *Fox News Sunday, CBS This Morning, Nightline, Meet the Press, Face the Nation, The NewsHour with Jim Lehrer* and *The Daily Show with Jon Stewart*.

In addition, Barnes hosts *Issues in the News* on Voice of America. Formerly, he was chief correspondent on the PBS series *National Desk* and host of *What's the Story?* on Radio America. Barnes authored the book *Rebel in Chief: Inside the Bold and Controversial Presidency of George W. Bush* in 2006 based on his exclusive interviews with top administration officials—as well as President Bush.

Over the years, he has written for *Reader's Digest*, *The New York Times, The Wall Street Journal*, *The Spectator*, *Washingtonian*, *The Public Interest*, *Policy Review* and both the *Sunday Telegraph* and *Sunday Times* of London.

The Media Guide has given Barnes four stars—its highest rating—and called him "a great political reporter-columnist" whose material is "exquisitely timed."

Barnes graduated from the University of Virginia and was a Neiman Fellow at Harvard University.

PAC Activity Report (2011-2012)

The Healthcare Distribution Management Association Political Action Committee (HDMA PAC) is a qualified, multi-candidate PAC registered with the Federal Election Commission. A component of the Association's advocacy efforts, the HDMA PAC is an effective way to become more politically active and support candidates who share the legislative priorities of primary distributors.

Every day, policies are considered by legislators that can have a long-term impact on the healthcare distribution industry, including:

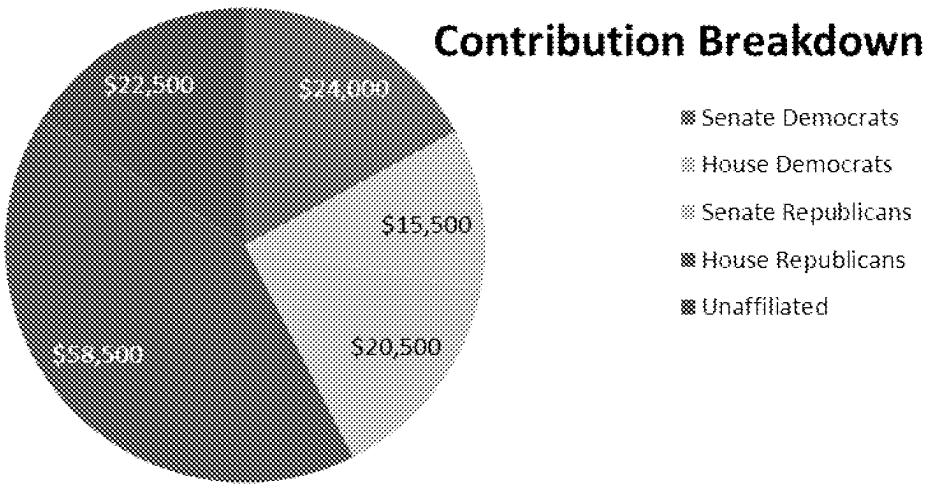
- Prescription drug anti-counterfeiting initiatives;
- Uniform pedigree requirements for prescription drugs;
- Controlled substances regulations;
- LIFO repeal and tax reform;
- Distributor licensure and accreditation;
- Medicaid/Medicare reimbursement; and,
- Influenza (pandemic and seasonal) and emergency response.

The purpose of the PAC is to provide campaign contributions to federal candidates for elective office who are interested in policy issues that advance the safe, secure and efficient delivery of lifesaving medicines; provide HDMA and our member companies with a greater ability to communicate with elected officials; and, inform and update PAC members about key legislative and regulatory issues affecting the healthcare distribution industry, HDMA member companies and customers.

- As of December 2012, 65 percent of the HDMA Board of Directors and 63 percent of eligible HDMA staff had contributed to the HDMA PAC.

- The total receipts exceeded $128,000 for the past election cycle (2011–2012).

- In the past election cycle, the HDMA PAC contributed $141,000 to federal candidates, the Republican Main Street PAC and the Senate Moderate Democrats PAC.

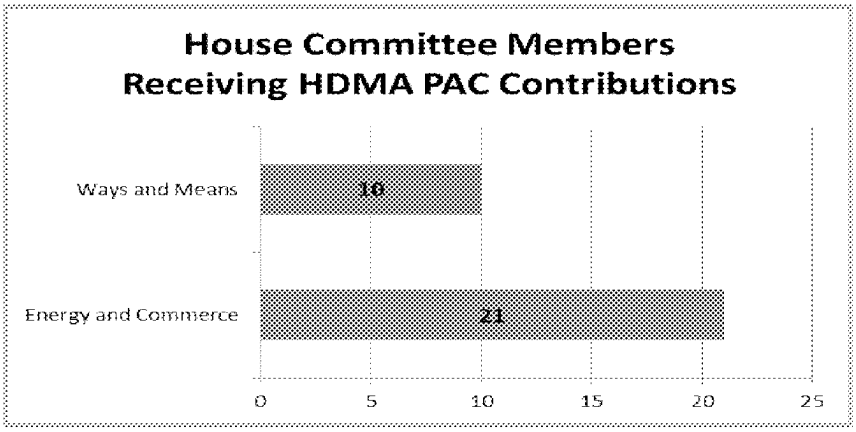


**Source for Chart: Federal Election Commission

HDMA PAC makes disbursement decisions through an active HDMA PAC Advisory Committee and selects recipients through a set of criteria identified in the HDMA PAC bylaws. HDMA PAC is authorized to make contributions to candidates for the United States House of Representatives and United States Senate, as well as to registered political committees established by federal candidates and political parties.

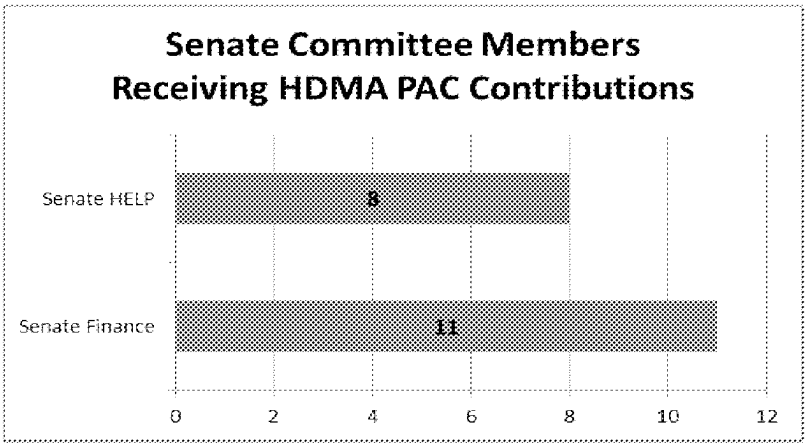
HOUSE OF REPRESENTATIVES

In making contribution decisions, HDMA PAC gives to candidates on key committees, such as the House Energy and Commerce Committee and the House Ways and Means Committee, as well as leadership. Additionally, HDMA PAC works to recognize champions on both sides of the aisle who meet its contribution criteria guidelines.



U.S. SENATE

In the Senate, HDMA PAC recognizes key members of the Senate Finance Committee and the Senate Health, Education, Labor and Pensions Committee. These committees have jurisdiction over many legislative priorities of interest to distributors.



For more information about the HDMA PAC, contact:
- Kristen Freitas, Senior Director, Federal Government Affairs, at (703) 885-0232 or kfreitas@hdmanet.org; or
- Jewelyn Cosgrove, Manager, Federal Government Affairs, at (703) 885-0272 or jcosgrove@hdmanet.org.

Please contact HDMA at any time should you wish to receive more information on HDMA PAC activities, congressional actions or advocacy opportunities.